UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,767	09/24/2003	Andreas Kage	71120	4380

23872 7590 03/29/2006

MCGLEW & TUTTLE, PC
P.O. BOX 9227
SCARBOROUGH STATION
SCARBOROUGH, NY 10510-9227

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,767	KAGE ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 24, 2003 with Applicant's cancellation of Claims 1-20 and with the addition of Claims 21-46. As the claims are drawn to more than one invention, a restriction requirement is deemed necessary, as set forth below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-23, drawn to a method of inhibiting the transition of cell free human immunodeficiency virus HIV) through the cellular mucosal barrier of an organism, the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, the method comprising: blocking the glycoprotein against said transition by increasing in the region of the mucosal barrier the concentration of a compound comprising at least one glycan comprising a terminal oligo mannosyl glycan residue for blocking the glycoprotein, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to the HIV remains unaffected, classified in class 514, subclass 23.

II. Claims 24-30, drawn to a method of inhibiting the transition of cell free Human Immunodeficiency Virus (HIV) through the cellular mucosal barrier of an organism, the HIV carrying an envelope glycoprotein gp120/gp160

which is linked to the HIV, the method comprising: blocking the glycoprotein against said transition by increasing in the region of the mucosal barrier the concentration of a compound comprising at least one glycan comprising a terminal oligomannosyl glycan residue for blocking the glycoprotein, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to the HIV remains unaffected; and wherein the increasing of the concentration of said compound in the region of said barrier is effected by local administration of said compound to said barrier, classified in class 514, subclass 23.

III. Claims 31-35, drawn to a method for treating an organism infected with cell free Human Immunodeficiency Virus (HIV), the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, and the organism having a cellular mucosal barrier, the method comprising: administering to the organism a compound comprising at least one glycan comprising a terminal oligo mannosyl glycan residue for blocking the glycoprotein against transition of the HIV through the cellular mucosal barrier, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to the HIV remains unaffected; and also administering to the organism a pyrimidine nucleoside analogue capable of inhibiting reverse transcriptase., classified in class 514, subclass 85.

IV. Claims 36-37, drawn to a method of inhibiting the transition of cell free Human immunodeficiency virus (HIV) through the cellular mucosal barrier of an organism, the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, the method comprising: blocking the glycoprotein against said transition by increasing in the region of the mucosal barrier the concentration of a compound comprising at least one glycan comprising a terminal oligomannosyl glycan residue for blocking the glycoprotein, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to the HIV remains unaffected; and wherein the increasing of the concentration of said compound in the region of said barrier is effected by stimulation of the p-andrenergic system within said organism, classified in class 514, subclass 23.

V. Claims 38-41, drawn to a method of inhibiting the transition of cell free Human Immunodeficiency Virus (HIV) through the cellular mucosal barrier of an organism, the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, the method comprising: blocking the glycoprotein against said transition by increasing in the region of the mucosal barrier the concentration of a compound comprising at least one glycan comprising a terminal oligomannosyl glycan residue for blocking the glycoprotein, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link

of the glycoprotein to the HIV remains unaffected; and wherein the increasing of the concentration of said compound in the region of said barrier is effected by inhibition of the endogenic processing of glycans by administration to said organism of an inhibitor of the endogenic processing of glycans, classified in class 514, subclass 23.

VI. Claims 42-43, drawn to a method for preventing an infection of a human subject with cell free Human Immunodeficiency Virus (H1V) by transition of the HIV through the cellular mucosal barrier of said subject, the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, the method comprising: administering locally topically to the sexual body part epithelial tissue region of said subject prior to sexual contact with another human subject a compound comprising at least one glycan comprising a terminal oligo mannosyl glycan residue for blocking the glycoprotein against said transition, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to the HIV remains unaffected., classified in class 514, subclass 23.

VII. Claims 44-46, drawn to a method for preventing an infection of a human subject with cell free Human Immunodeficiency Virus (H1V) by transition of the HIV through the cellular mucosal barrier of said subject, the HIV carrying an envelope glycoprotein gp120/gp160 which is linked to the HIV, the method comprising: administering locally topically to the sexual body

epithelial tissue region of said subject prior to sexual contact with another human subject a compound comprising at least one glycan comprising a terminal oligo mannosyl glycan residue for blocking the glycoprotein against said transition, said terminal oligo mannosyl glycan residue being non-sulphated and non-ionic, and wherein in blocking the glycoprotein, the link of the glycoprotein to HIV remains unaffected and also administering to the first aforesaid subject a pyrimidine nucleoside analogue capable of inhibiting reverse transcriptase, classified in class 514, subclass 85.

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the seven different group are directed to seven different inventions comprising the administration of different combinations of different ingredients to provide different functional effects.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 18, 2006